

## **REMARKS**

### **Status of the claims:**

The following remarks are submitted in response to the Office Action mailed February 15, 2007. Prior to entry of the above amendments, claims 1-63 are pending in the present application.

Claims 13-15, 34-37, 39, and 41-46 are canceled without prejudice to their re-entry in a separate application.

Claims 1, 2, 7, 10, 11, 16, 18, 19, 23, and 24 have been amended.

Claims 47-63 are withdrawn by the Examiner as being drawn to a non-elected invention.

Claims 31, 34-37, 39 and 41-46 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement.

Claims 1-46 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting.

Claims 1-4, 7-11, 13-17, 22, 24, and 26-46 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Robl '506 (WO 2000/59506), Yasuda '391 (CA 105:210391), or Schneiders '079 (CA 77:68079).

Claims 1-4, 7-17, 19, 20, 22, 24, and 26-46 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Robl '506.

### **Scope of Examination**

In the Office Action mailed February 15, 2007, the Examiner required that the claims be limited in scope to the subject matter examined with the following substitutions on Formula (I) in claim 1: W is N(R<sub>2</sub>); Ar<sub>1</sub> is an optionally substituted phenyl group; Ar<sub>2</sub>

is an optionally substituted phenyl group; T is an optionally substituted phenyl group; L<sub>2</sub> is a direct bond; and all other variables are as defined.

As a result of the election and the corresponding scope of the invention examined by the Examiner, the remaining subject matter in claims 1-10, 12-26, and 30 was withdrawn from consideration by the Examiner.

### **Claim Amendments**

With the above amendments, claims 1, 2, 7, 10, 11, 16, 18, 19, 23, and 24 have been amended. No new matter has been added by way of the above amendments. Support for the amendment to claim 1 can be found in original claims 7, 10, and 16 among other places. All other amendments are for stylistic reasons or to place the claims within the scope of the Examiner's restriction requirement/election of species. Reconsideration is respectfully requested in light of the following remarks.

### **Election**

Applicants respectfully point out that the compound that was elected was Example 320, not Example 319 (*i.e.*, 4-[2-[2-(4'-butoxy-biphenyl-4-yl)-(E)-vinyl]-4-(2,4-dichloro-phenyl)-imidazol-1-ylmethyl]-benzoic acid). In the response to the Examiner's restriction requirement/election of species, Applicants mis-identified the compound. The Examiner did search the correct compound.

### **Claim Objections**

Claim 44 is objected to for misspelling "pharmaceutical". Applicants have canceled claim 44 so the objection is moot. Withdrawal of the objection is warranted and respectfully requested.

**Rejections under 35 U.S.C. §112, first paragraph**

Claims 31, 34-37, 39 and 41-46 are rejected under 35 U.S.C. §112, first paragraph as allegedly not being enabled.

Applicants traverse.

While Applicants disagree with the Examiner's basis for rejecting claims 31, 34-37, 39 and 41-46 under 35 U.S.C. §112, first paragraph as allegedly not being enabled, in the interest of expediting allowance of this application, Applicants have canceled claims 34-37, 39 and 41-46 so the rejection is moot with respect to those claims. Applicants reserve the right to submit these claims in a separate application.

Contrary to the Examiner's statement, Applicants submit that with regard to claim 31 a composition can be made and used without undue experimentation that contains one or more of alkylating agents, antimetabolites, plant alkaloids, antibiotics, hormones, biologic response modifiers, analgesics, NSAIDs, DMARDs, glucocorticoids, sulfonylureas, biguanides, acarbose, PPAR agonists, DPP-IV inhibitors, GK activators, insulin, insulin mimetics, insulin secretagogues, insulin sensitizers, GLP-1, GLP-1 mimetics, cholinesterase inhibitors, antipsychotics, antidepressants, anticonvulsants, HMG CoA reductase inhibitors, cholestyramine, or fibrates. Examples of these compounds are listed in paragraphs [1374] to [1399] thereby enabling the full scope of this claim. Further, Applicants submit that the components enumerated in these paragraphs could easily be added to the compounds of the present invention to make a composition that can be made and used without undue experimentation. Further, the level of skill in the art was high at the time of filing of the present application. In fact, the techniques involved in preparing a pharmaceutical formulation recited in claim 31 were well known in the art even before the filing date and can be readily practiced by one of skill in the art.

For the above reasons, Applicants submit that the enablement rejection is inapposite. Withdrawal of the rejection is warranted and respectfully requested.

### **Double Patenting**

Claims 1-46 have been rejected under judicially created obviousness type double patenting as being unpatentable over claims 1-16, 19-26, 28-52 and 70 of co-pending Application No. 11/056,498.

Applicants traverse.

MPEP 804 recites:

*If a "provisional" nonstatutory obviousness-type double patenting (ODP) rejection is the only rejection remaining in the earlier filed of the two pending applications, while the later-filed application is rejectable on other grounds, the examiner should withdraw that rejection and permit the earlier-filed application to issue as a patent without a terminal disclaimer. If the ODP rejection is the only rejection remaining in the later-filed application, while the earlier-filed application is rejectable on other grounds, a terminal disclaimer must be required in the later-filed application before the rejection can be withdrawn.*

Applicants respectfully request that should all rejections be obviated that the Examiner allow the present invention to issue and maintain the rejection over co-pending Application No. 11/056,498 because the instant application has a filing date that precedes that of co-pending Application No. 11/056,498 (i.e., February 12, 2004 v. February 11, 2005, respectively).

### **Rejections under 35 U.S.C. § 102**

Claims 1-4, 7-11, 13-17, 22, 24, and 26-46 are rejected under 35 U.S.C. 102(b) as allegedly being anticipated by Robl '506 (WO 2000/59506), Yasuda '391 (CA 105:210391), or Schneiders '079 (CA 77:68079).

Applicants traverse.

Applicants have amended claim 1 so that none of the cited compounds fit within the genus of the present invention. The amendment to L<sub>1</sub> in claim 1 obviates any of the compounds from the recited references. All other claims are either directly or indirectly dependent from claim 1. Applicants believe that with this amendment to claim 1 that the rejection has been obviated. Withdrawal of the rejection is warranted and respectfully requested.

### **Rejections under 35 U.S.C. § 103**

Claims 1-4, 7-17, 19, 20, 22, 24, and 26-46 are rejected under 35 U.S.C. §103(a) as being unpatentable over Robl '506. Applicants traverse.

To establish a proper case of obviousness, one must apply the *Graham v. John Deere* factors. These factors include:

- (A) Determining the scope and contents of the prior art;*
- (B) Ascertaining the differences between the prior art and the claims in issue;*
- (C) Resolving the level of ordinary skill in the pertinent art; and*
- (D) Evaluating evidence of secondary considerations.*

See *Graham v. John Deere*, 383 U.S. 1, 148 USPQ 459 (1966).

Moreover, recently in the *KSR* case, regarding obviousness, the Court held

*Often, it will be necessary . . . to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis should be made explicit. See In re Kahn, 441 F. 3d 977, 988 (CA Fed. 2006) ([R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness).*

See KSR International Co. V. Teleflex Inc. et al. (Bench Opinion No. 04-1350.)

When the John Deere factors and the holding in KSR are considered in light of the rejection presented, one can only conclude the instantly claimed invention is non-obvious for the following reasons.

Claim 1 has been amended so that there is no overlap between the instantly claimed genus and the genus disclosed in Robl '506. For example, Robl '506 fails to disclose or remotely suggest anything other than a phenylene group that is attached directly to the imidazole (see for example, formula I on page 2 in Robl '506). Accordingly, because there is no overlap between the genus of the present invention and the genus in Robl '506, Applicants submit that Robl '506 can not render the present invention *prima facie* obvious.

Withdrawal of the rejection is warranted and respectfully requested.

### **Fees**

The Office Action mailed February 15, 2007 set a shortened statutory period of three months for a reply. This Response is being filed before July 15, 2007, thus a petition for a two month extension of time and the associated fee is included with this Response.

No additional fee is believed due, however, should a fee be deemed to be necessary, the Commissioner is hereby authorized to charge any fees required by this action or any future action to Deposit Account No. 16-1435.

### **CONCLUSION**

With the above amendments and remarks, Applicants believe that all objections and/or rejections have been obviated. Thus, each of the claims remaining in the

application is in condition for immediate allowance. A passage of the instant invention to allowance is earnestly solicited.

Should the Examiner have any questions relating to the instant application, the Examiner is invited to telephone the undersigned at (336) 607-7486 to discuss any issues.

Respectfully submitted,

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Ben Schroeder  
T. Benjamin Schroeder (Reg. No. 50,990)

KILPATRICK STOCKTON LLP  
1001 West Fourth Street  
Winston-Salem, North Carolina 27101-2400  
Phone: (336) 607-7486  
Facsimile: (336) 607-7500